Exhibit 300: Capital Asset Summary

Part I: Summary Information And Justification (All Capital Assets)

Section A: Overview & Summary Information

Date Investment First Submitted: 2009-06-30
Date of Last Change to Activities: 2012-07-23
Investment Auto Submission Date: 2012-02-27
Date of Last Investment Detail Update: 2012-04-02
Date of Last Exhibit 300A Update: 2012-07-23
Date of Last Revision: 2012-07-23

Agency: 009 - Department of Health and Human Services **Bureau:** 10 - Food and Drug Administration

Investment Part Code: 01

Investment Category: 00 - Agency Investments

1. Name of this Investment: FDA CDER MedWatch Plus

2. Unique Investment Identifier (UII): 009-000005315

Section B: Investment Detail

1. **Provide a brief summary of the investment, including a brief description of the related benefit to the mission delivery and management support areas, and the primary beneficiary(ies) of the investment. Include an explanation of any dependencies between this investment and other investments.**

The Food and Drug Administration (FDA) is responsible for monitoring the safety of FDA regulated products in order to protect and promote public health. Analysis of adverse event and safety report information is critical to achieving this goal. The FDA needs to modernize its aging systems, improve its analytic capabilities, and make it easier for the public to submit adverse event and safety reports to the FDA. FAERS (FDA Adverse Event Reporting System) is a Web-based Oracle database application and Business Intelligence data warehouse that will replace legacy AERS (Adverse Event Reporting System). FAERS will contain post-market adverse event reports associated with drugs and biologic products. These adverse event reports are submitted to FDA by manufacturers, healthcare professionals, and consumers. FDA will use FAERS for regulatory compliance, and to monitor for adverse events and medication errors that might occur with approved products. FAERS is an Oracle operational database. Operational databases can store large amounts of data, and allow users to quickly enter, revise, and retrieve information from one system. When FAERS replaces AERS, FAERS will contain more than six million adverse event reports, and the dataset will continually change as new reports or follow up information is entered into the database.

2. **How does this investment close in part or in whole any identified performance gap in support of the mission delivery and management support areas? Include an assessment of the program impact if this investment isn't fully funded.**

FAERS directly supports Federal mandate to collect adverse event reporting as defined in 42 CFR §310.305, §314.80, §314.98 and §600.80. This effort supports the goal of e-Government by creating consolidated and efficient electronic access to adverse event reporting information. This, along with the system's capabilities of accepting adverse event reports, facilitates real-time transfer of information, improves the FDA's responsiveness to the American public, consumers, industry, and healthcare providers. FAERS provides enhanced analyses to support safety evaluators and other Agency medical officers with appropriate tools to conduct analytic processes and reporting. This will be accomplished through a robust adverse event report system enabling daily decision-making, on-demand adverse event reporting by safety evaluators and medical officers. FAERS will provide consistent and prompt adverse event reports to the user community, Congress, FOIA, health care industry, manufacturing organizations, as well as a host of other external stakeholders. FAERS will subsume a myriad of aging legacy and disparate systems, ultimately providing enhanced capabilities for adverse event reporting. This System provides a technology upgrade in both hardware and software to meet the growing demand of functionality and performance from business. The Enterprise Architecture of FAERS provides the optimal platform for continued program expansion, such as the expanded automation of data mining and ongoing safety issues to support Federal mandates. This investment facilitates a robust pharmacovigilance and analytic process for adverse event reporting and tracking. Disparate systems will be subsumed by FAERS. As a result of FAERS, business processes will be streamlined, creating efficiencies in work-flow processes for its user communities. This project seeks to bridge multiple gaps within the CDER and CBER adverse event reporting domain. This project seeks to create a higher level of adverse event consistency, as well as data integrity. If this project is not fully funded, adverse event reporting will be compromised and user communities will not be able to efficiently and effectively analyze, report and track adverse event reporting.

3. **Provide a list of this investment's accomplishments in the prior year (PY), including projects or useful components/project segments completed, new functionality added, or operational efficiency achieved.**

Accomplishments for CDER/CBER in FY11 include Release 1.0 containing drug class queries, 15-day reporting, workflow & analysis for lipid lowering drugs; Release 2.0 containing Data Entry, eSub, Dictionary Mgmt, select reports and two Oracle COTS patches. In FY12 completed Release 2.1 containing batch printing, bar code labeling, one OAERS COTS patch, and Personal Identity Verification (PIV) on all environments. Established FAERS Business Intelligence Solution (FBIS) to meet FDA safety evaluator needs for complex querying. Release 2.1 included FBIS FOI Reports. Accomplishments for CDRH in FY11 include Proof of Concept Evaluation and Alternatives Analysis, delivery of Release 3.0 which provided design framework for workflow. Completed an alternatives analysis of platform options for CDRH FAERS. Pursuing an independent verification and validation (IV&V) step before making final technology decision.

4. **Provide a list of planned accomplishments for current year (CY) and budget year (BY).**

FY12 CDER/CBER Release 2.2 to deploy additional dictionary functionality; deliver FBIS

Phase II containing: FOI enhancements, Quick Query Reports (levels I & II) and Designated Alert Summary Reports (DASR Levels I, II & III); provide end-user training; transition off Legacy AERS. FY12 CDER/CBER: Release 2.3 Production "Stabilization release" - deploy customized enhancement to Quick Query functionality, incorporation of additional reports, batch printing. FY13 CDER/CBER FAERS – DQRS: Release 4.0; Add DQRS functionality into CDER/CBER FAERS and retire legacy system. FY12 CDRH FAERS: Complete IV&V, finalize technology decision, and complete planning for upcoming releases. FY13 CDRH FAERS: Release 5.0; Builds on release 3.0 functionality to detect/evaluate signals.

5. **Provide the date of the Charter establishing the required Integrated Program Team (IPT) for this investment. An IPT must always include, but is not limited to: a qualified fully-dedicated IT program manager, a contract specialist, an information technology specialist, a security specialist and a business process owner before OMB will approve this program investment budget. IT Program Manager, Business Process Owner and Contract Specialist must be Government Employees.**

2010-12-01

Section C: Summary of Funding (Budget Authority for Capital Assets)

1.

Table I.C.1 Summary of Funding

	PY-1 & Prior	PY 2011	CY 2012	BY 2013
Planning Costs:	$4.8	$0.6	$0.7	$0.2
DME (Excluding Planning) Costs:	$40.1	$7.8	$1.7	$1.7
DME (Including Planning) Govt. FTEs:	$3.0	$2.4	$0.7	$0.7
Sub-Total DME (Including Govt. FTE):	$47.9	$10.8	$3.1	$2.6
O & M Costs:	$4.0	$3.7	$1.7	$2.5
O & M Govt. FTEs:	$0.5	$0.1	$0.3	$0.6
Sub-Total O & M Costs (Including Govt. FTE):	$4.5	$3.8	$2.0	$3.1
Total Cost (Including Govt. FTE):	$52.4	$14.6	$5.1	$5.7
Total Govt. FTE costs:	$3.5	$2.5	$1.0	$1.3
# of FTE rep by costs:	34	10	7	11
Total change from prior year final President's Budget ($)		$2.9	$-3.3	
Total change from prior year final President's Budget (%)		24.29%	-40.09%	

2. If the funding levels have changed from the FY 2012 President's Budget request for PY or CY, briefly explain those changes:

FY11 costs increased as a result of expansions in the CDER/CBER FAERS scope to include a business intelligence data warehouse, enhanced product dictionary & searching/reporting to meet Science Board recommendations. Due to anticipated technology obsolescence, CDRH has completed an alternatives analysis of platform options & are pursuing an IV&V step before making a final technology decision. The result is a reduction in FY12 development funding requirements while the IV&V process takes place.

Section D: Acquisition/Contract Strategy (All Capital Assets)

Table I.D.1 Contracts and Acquisition Strategy

Contract Type	EVM Required	Contracting Agency ID	Procurement Instrument Identifier (PIID)	Indefinite Delivery Vehicle (IDV) Reference ID	IDV Agency ID	Solicitation ID	Ultimate Contract Value ($M)	Type	PBSA ?	Effective Date	Actual or Expected End Date
Awarded		HHSF223201000014I									
Awarded		HHSF223200950026I									
Awarded		HHSF223200950021									

2. If earned value is not required or will not be a contract requirement for any of the contracts or task orders above, explain why:

Exhibit 300B: Performance Measurement Report

Section A: General Information

Date of Last Change to Activities: 2012-07-23

Section B: Project Execution Data

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
290069	CDER/CBER FAERS	The Food and Drug Administration (FDA) is responsible for monitoring the safety of FDA regulated products in order to protect and promote public health. Analysis of adverse event and safety report information is critical to achieving this goal. The FDA needs to modernize its aging systems, improve its analytic capabilities, and make it easier for the public to submit adverse event and safety reports to the FDA. FAERS (FDA Adverse Event Reporting System) is a Web-based Oracle database application and Business Intelligence data warehouse that will replace legacy AERS (Adverse Event Reporting System). FAERS will contain post-market adverse event reports associated with drugs and biologic products. These adverse event reports are submitted to FDA by manufacturers,			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		healthcare professionals, and consumers. FDA will use FAERS for regulatory compliance, and to monitor for adverse events and medication errors that might occur with approved products. FAERS is an Oracle operational database. Operational databases can store large amounts of data, and allow users to quickly enter, revise, and retrieve information from one system. When FAERS replaces AERS, FAERS will contain more than six million adverse event reports, and the dataset will continually change as new reports or follow up information is entered into the database.			
290070	CDRH FAERS	The CDRH FAERS is to provide CDRH and other stakeholders with a modernized adverse event reporting system. The FDA post market safety surveillance goals are to maintain and continue to build an adverse event reporting system, increase FDA operational efficiency and support international and national public health partnerships. The CDRH FAERS project will replace the Center's current legacy adverse event (AE) system (MAUDE). The purpose of this project is to improve the CDRH post-market product safety surveillance capabilities by providing better individual safety report handling and enhanced signal detection. Adverse Event Reporting is a critical element of the Agency's post-market safety surveillance			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		program for all FDA-regulated products. CDRH FAERS is one project related to the multi-Center initiative for enhanced AE reporting. The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) are also developing a solution for AE reporting. In addition, this project is working with participation by internal stakeholders, customers, Office of Information Management (OIM) partners, Office of Combination Products and subject matter experts (SMEs).			
307741	CDER/CBER FAERS: Drug Quality Reporting System (DQRS)	This project will incorporate Drug Quality Reporting System (DQRS) functionality into FAERS and retire the legacy DQRS system. Since the early 1970s, the FDA has operated the Drug Quality Reporting System (DQRS), which encourages health care professionals to voluntarily report observed or suspected defects or quality problems with marketed drug products. The Division of Compliance Risk Management and Surveillance evaluates and prioritizes drug quality reports in order to identify and follow-up on significant health hazards through assignment and review of investigative reports. Drug quality reports are also used to identify industry trends associated with pharmaceutical manufacturing, packaging, and labeling. These product quality			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		reports are also part of the FDA's post-marketing safety surveillance program and FAERS users should have the ability to analyze these reports in conjunction with adverse event reports. Having an integrated solution instead of the current separate systems will help reduce the total maintenance costs.			

Activity Summary

Roll-up of Information Provided in Lowest Level Child Activities

Project ID	Name	Total Cost of Project Activities ($M)	End Point Schedule Variance (in days)	End Point Schedule Variance (%)	Cost Variance ($M)	Cost Variance (%)	Total Planned Cost ($M)	Count of Activities
290069	CDER/CBER FAERS							
290070	CDRH FAERS							
307741	CDER/CBER FAERS: Drug Quality Reporting System (DQRS)							

Key Deliverables

Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
290069	290069: Release FY10 Release 1.0 (Drugs/Biologics)	FY10 Release 1.0 (Drugs/Biologics) Drug class queries and 15-Day Reporting	2011-04-30	2011-04-30	2011-04-30	227	0	0.00%
290069	290069: Drugs/Biologics Planning	Planning and Requirements in support of subsequent releases	2011-08-01	2011-08-01	2011-08-01	48	0	0.00%
290069	290069: Release	FY10 Funding	2011-09-30	2011-09-30	2011-09-30	152	0	0.00%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
	FY10 Funding Release 2.0 (Drugs/Biologics)	Release 2.0 (Drugs/Biologics) Retires legacy AERS, vastly improved product identification, user-definable dashboards & alerts.						
290070	290070: FY10 Funding Release 3.0 (Devices)	FY10 Funding Release 3.0 (Devices) Improves safety signal detection & evaluation.	2011-09-30	2011-09-30	2011-09-30	364	0	0.00%
290069	290069: Release 2.0 (Drugs/Biologics) Program Management	Govt Program Management including EPLC/Stage Gate deliverables in support of Release 2.0	2011-11-30	2011-11-30	2011-11-30	120	0	0.00%
290069	290069: Release 2.1 (Drugs/Biologics) Planning for 2.1 and subsequent releases	Business Analyst Support for rolling wave planning and on-going requirements/change management activities related to release 2.1 and subsequent releases	2012-01-31	2012-01-31	2012-01-31	61	0	0.00%
290069	290069: Release 2.1 (Drugs/Biologics) Program Management	Govt Program Management including EPLC/Stage Gate deliverables in support of Release 2.1	2012-01-31	2012-01-31	2012-01-31	61	0	0.00%
290069	290069: Release 2.2 (Drugs/Biologics) Planning for 2.2 and subsequent releases	Business Analyst Support for rolling wave planning and on-going requirements/change management activities related to release 2.2 and subsequent releases	2012-04-15	2012-04-15		74	-138	-186.49%

Key Deliverables

Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
290069	290069: Release 2.2 (Drugs/Biologics) Program Management	Release 2.2 (Drugs/Biologics) Govt Program Management including EPLC/Stage Gate deliverables in support of Release 2.2	2012-04-15	2012-04-15		74	-138	-186.49%
290070	290070: Release 3.5 (Devices) - Gov't FTEs	FY12 Gov't FTE in support of Release 3.5 Development and Planning	2012-09-30	2012-09-30		365	0	0.00%

Section C: Operational Data

Table II.C.1 Performance Metrics

Metric Description	Unit of Measure	FEA Performance Measurement Category Mapping	Measurement Condition	Baseline	Target for PY	Actual for PY	Target for CY	Reporting Frequency
Reduction in Operations and Maintenance Costs	$	Technology - Technology Costs	Under target	2.985000	2.600000		1.500000	Semi-Annual
Cost avoided by eliminating a separate drug quality system	$	Process and Activities - Financial	Over target	0.000000	0.000000		131250.000000	Semi-Annual
Time for retrieval of complete product information including manufacturing, regulatory, substance and labeling.	Hours	Process and Activities - Cycle Time and Timeliness	Under target	5.000000	5.000000	5.000000	5.000000	Monthly
Length of time from receipt of a non-electronic report until report is available in a database for reviewers	Days	Mission and Business Results - Management of Government Resources	Under target	14.000000	14.000000		10.000000	Semi-Annual
Percentage of concomitant drugs in adverse event reports with validated active ingredient or trade name	%	Customer Results - Customer Benefit	Over target	0.000000	0.000000		50.000000	Semi-Annual
Percentage validated OTC trade names in adverse event reports	%	Process and Activities - Productivity	Over target	0.000000	0.000000		50.000000	Semi-Annual
Percentage of electronic reports from manufacturers that must go through a manual process to validate a trade name since the trade name cannot be validated automatically against	%	Technology - Efficiency	Under target	30.000000	30.000000		20.000000	Semi-Annual

Table II.C.1 Performance Metrics

Metric Description	Unit of Measure	FEA Performance Measurement Category Mapping	Measurement Condition	Baseline	Target for PY	Actual for PY	Target for CY	Reporting Frequency
existing dictionary								